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EXAMINER	
MCALLISTER, STEVEN B	
ART UNIT	**PAPER NUMBER**
3627	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/849,625	MCGRADY ET AL.	
	Examiner	Art Unit	
	Steven B. McAllister	3627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

Regarding the Elections requirement, the examiner withdraws the requirement and rejoinds all withdrawn claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-9 and 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites that step (e) includes providing an input "indicative that the second quantity of the first type of medical item has been stocked at the remote storage location." However, in claim 1 the data of step (e) is recited as "indicative of the use of a second quantity of the first type of medical item". The use of the term "use" is unclear. It is not clear how the item is being used by sitting in a second storage location. It would appear that its use would occur when it is administered.

Claim 11 is indefinite because it recites "a second quantity" of the first type of the medical item, but "a second quantity" has been previously recited in claim 1, from which claim 11 depends. It is unclear whether the two recitations refer to the same thing (in which case the second recitation should be "the"), or whether they refer to two different

things, in which case the second recitation should be recited in such a way as to differentiate it from the first.

Further, claim 1 refers to the "first quantity" being removed for use in an activity and a "second quantity" actually being used in the activity. Claim 10 appears to recite that the activity referred to in claim 1 is a compounding activity. Therefore, it appears that the second recitation of the "second quantity" would refer to the amount actually used in the compounding activity, leaving a different amount which is wasted as recited in claims 11 and 13.

Note Regarding Examination

In the previous Office Action, the examiner stated that certain subject matter was common knowledge or old and well known. Per MPEP 2144.03(C), Applicant must adequately traverse the statements that something is old and well, or common knowledge in the subsequent response. It is noted that the traversals presented in the subsequent response are inadequate because "To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would *include stating why the noticed fact is not considered to be common knowledge or well-known in the art.*" MPEP 2144.03(C). A statement indicating why the noticed fact is not considered to be common knowledge or old and well known was not included in the subsequent response.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 10, 11, 15, 19, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by King et al (WO 98/50840).

King et al disclose a method comprising storing a plurality of medical items in a plurality of storage locations within a pharmacy (e.g., individually controlled storage spaces in a vault); storing data in a data store corresponding to the medical items (since e.g., requesting access to a particular item only allows a certain compartment to open); providing input indicative of taking a first quantity of a first type of medical item from a first storage location for use in second location outside of the pharmacy; and providing input indicative of the use of a second quantity of the items at the second location; including in the data store data responsive to the inputs; and comparing at least a portion of the data included in steps (d) through (f).

As to claims 2 and 3, King et al show tracking the amount sent to remote storage, tracking the amount removed from remote storage, and determining automatically when the amount remaining in remote storage falls below a certain threshold (e.g., pg. 7, last

par. – pg. 8, top par.). The remaining amount in the remote storage is indicative of the difference between the data in step (d) and step (f), the first and second quantities.

As to claim 10, King et al show providing an input indicative of use of a first quantity in a compounding activity.

As to claim 11, King et al show wasting another quantity.

As to claim 15, King et al show borrowing a third quantity of medical item from another facility; providing at least one input indicative of borrowing the item and storing the information. (see e.g., p. 19, Table 6, p. 10, #8).

As to claim 19, King et al show lending a third quantity of a second item; providing at least one input indicative of lending the item and storing the information. (see e.g., p. 19, Table 6, p. 10, #8).

As to claims 20, King et al show all elements (see e.g., DEA 222 generated with drug information filled in by system).

As to claim 23, King et al show the software performing the method of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 16-18, 21, 22, 24 and 25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over King et al.

As to claim 4, King et al show all elements of the claim including indication the absence of data related to the first medical item since the system tracks and audits the drugs and such auditing of the tracked drugs reveals missing drugs and information.

As to claim 4, King et al show all elements of the claim except noting the absence of data related to the first type of medical item. However, the examiner takes official notice that it is notoriously old and well known in the art to provide an indication of missing data related to a tracked item. It would have been obvious to one of ordinary skill in the art to modify the method of King et al by indicating the missing information in order to flag missing or incorrectly logged items.

As mentioned in the 112 2d rejection of claims 5-9, it appears in claim 5 recites providing an indication of a first quantity for stocking at a remote location, as opposed to claim 1's recitation of providing an indication of a first quantity for use, and that claim 5 recites providing an input of a second quantity which is actually becomes stocked at the remote location, as opposed to claim 1' s recitation of an input indicative of use of a second quantity. Rather, it appears that the use occurs in claim 6.

Claims 5-9 are examined in light of this interpretation.

As to claims 1 and 5, King et al disclose a method comprising storing a plurality of medical items in a plurality of storage locations within a pharmacy (e.g., individually

controlled storage spaces in a vault); storing data in a data store corresponding to the medical items (since e.g., requesting access to a particular item only allows a certain compartment to open); providing input indicative of taking a first quantity of a first type of medical item from a first storage location for stocking in a second location outside of the pharmacy; and providing input indicative of the storage of a second quantity of the items at the second location; including in the data store data responsive to the inputs; and comparing at least a portion of the data included in steps (d) through (f). It is inherent that the second quantity actually stocked at the remote location is input and that at least a portion of the data are compared since the system of King tracks the movement of controlled substances throughout the facility and produces inventories and audits, reporting missing drugs; and in order to produce such inventories, audits, and reports of missing drugs, it is necessary to carry out those steps (also, see tracking of items taken to remote storage but not entered into the system – Table 3).

Alternatively, King shows all elements except providing an input of the amount stocked in the remote location and comparing at least a portion of the data of steps (d) through (f). However, the examiner takes official notice that it is notoriously old and well known in the art to provide an input of the amount stocked in the remote location and to compare at least a portion of the data of steps (d) through (f). It would have been obvious to one of ordinary skill in the art to modify the method of King by doing so in order to enable accurate tracking, inventory and detection and reporting of missing drugs.

As to claims 6-9, King performs all steps (see e.g., p. 11 of King).

As to claim 16, King et al inherently show storing data representative of the third quantity of the second type of medical item in at least one storage location in the pharmacy, since the system and method of King provides associates all incoming material with a storage location.

Alternatively, King et al show all elements except storing the location data. However, the examiner takes official notice that it is notoriously old and well known in the art to store information indicative of a storage location in the pharmacy. It would have been obvious to one of ordinary skill in the art to modify the method of King by doing so in order to provide for efficient access to the third medical item.

As to claim 17, King et al inherently shows all steps of the claim since it tracks the borrowing of items, and part of the process of borrowing is returning the item.

Alternatively, King et al show all elements except returning the third quantity of the item, providing an input indicative of the returning of the third quantity of the item and storing the data. However, the examiner takes official notice that it is notoriously old and well known in the art to perform these steps. It would have been obvious to one of ordinary skill in the art to further modify the method of King by doing so in order to ensure that the lender will lend items in the future and in order to provide accurate tracking of the item.

As to claim 18, King et al show all elements.

As to claim 21, King et al show all elements, including at least one field filled in automatically by the processor (see e.g., the type of drug filled in by system in Table 6).

Alternatively, King et al show all elements except that at least one field is automatically populated. However, the examiner takes official notice that it is notoriously old and well known in the art to populate at least one field of an electronic form automatically. It would have been obvious to one of ordinary skill in the art to do so in order to speed the process of filling out the form and to reduce the chance of errors.

As to claim 22, King et al shows all elements since receiving a return of the third quantity of the item is part of the process of lending the item and the system performs tracking of all lent items.

Alternatively, King shows all elements of the claim except receiving a return of the third quantity of the second item, providing an input indicative of the return, and storing the data. However, the examiner takes official notice that it is notoriously old and well known in the art to perform these steps. It would have been obvious to do so in order to ensure that permanent loss of inventory does not occur, and to perform tracking of all lent and returned items.

As to claim 24, King et al show all elements of the claim. King shows all elements, as discussed regarding at least claims 1-3, and further shows storing medical

items in locations where items in one location have different characteristics than items in a second location (e.g., see p. 9, lines 3-19); storing data linking characteristics to storage locations, first and second items being linked to different locations. It shows comparing the quantity taken and the quantity used and providing an output indicative of the difference (e.g., comparing the amount taken from the pharmacy for storage and later use in the hospital to the amount actually used to determine the amount in the remote storage location; also comparing to detect missing or diverted drugs).

Alternatively, King shows all elements except comparing the data stored in (d) and (f) and producing an output indicative of the difference. However, the examiner takes official notice that it is notoriously old and well known in the art to perform these steps. It would have been obvious to do so in order to perform accurate tracking of drugs, or detect missing or diverted drugs or maintain accurate inventory.

As to claim 25, King et al show all elements of the claim. King shows all elements, as discussed regarding at least claims 1-3, and further shows storing medical items in locations where items in one location have different characteristics than items in a second location (e.g., see p. 9, lines 3-19); storing data linking characteristics to storage locations, first and second items being linked to different locations. It shows removing a first amount; storing data representative of that amount; wasting a second amount; storing data representative of the second amount; comparing the quantity taken and the quantity wasted.

Alternatively, King shows all elements except comparing the data stored in (d) and (f). However, the examiner takes official notice that it is notoriously old and well known in the art to perform these steps. It would have been obvious to do so in order to perform accurate tracking of drugs, or detect missing or diverted drugs, or maintain accurate inventory.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al.

As to claim 12, King et al show creating a compound; providing an input indicative of storing in a pharmacy the compound created; and including in the data store the resulting data (see e.g., p. 10, #4, p. 22, Table 9). King et al do not explicitly show that the location of the compound in the pharmacy is indicated or stored. However, the examiner takes official notice that it is notoriously old and well known in the art to indicate and store the location of a drug, including a compounded drug, in a pharmacy. It would have been obvious to one of ordinary skill in the art to modify the method of King et al by doing so in order to provide efficient access to the compound.

As to claim 13, King et al show that the other quantity wasted is wasted in the compounding process (e.g., Table 9) and comparing the first, other quantity and the amount of compound since the system tracks the amount of both the first item and the compound, and tracks missing drugs and wasted drugs. For instance, it shows detecting a variance due overfill or underfill by the original medical item manufacturer.

As to claim 14, King et al practices all steps.

Alternatively, claims 13 and 14 show all elements except comparing the first quantity, other quantity and the amount of compound, and providing an input indicating a discrepancy responsive to the comparison and storing that data. However, the examiner takes official notice that it is notoriously old and well known in the art to perform these steps. It would have been obvious to one of ordinary skill in the art to further modify the method of King by performing these steps in order to determine and track discrepancies in the amount of drugs and compounds in the inventory.

Claims 1-4, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative under 35 U.S.C. 103(a) as being unpatentable over Lester et al (6,021,392) and Colella et al (6,003,006) incorporated by reference into Lester.

Lester et al disclose a method comprising storing a plurality of medical items in a plurality of storage locations within a pharmacy (see e.g., use of bar coded shelf labels as in Fig. 14 of Lester); storing data in a data store corresponding to the medical items (see e.g., col . 11, lines 1-12 of Lester); providing input indicative of taking a first quantity of a first type of medical item from a first storage location for use in second location outside of the pharmacy; and providing input indicative of the use of a second quantity of the items at the second location (see e.g., col. 4, lines 1-26 of Colella). Lester and Colella further show comparing amount removed to a second location and

the amount used, since the automatically tracks inventory in order to provide for re-ordering of drugs, and in order to determine the amount of the drug within the hospital system (the pharmacy and DDM's) and in order to determine the amount in a DDM, the amount sent to the DDM and the used must be compared.

Alternatively, Lester and Colella teach all elements except comparing the amount removed to a second location and the amount used. However, the examiner takes official notice that it is notoriously old and well known in the art to compare the amount in and the amount out in order to prevent loss. It would have been obvious to one of ordinary skill in the art to modify the method of Lester/Colella by comparing the amount removed to a second location and the amount used in order to reduce loss and theft.

As to claim 23, the computer readable media operative to carry out the method steps is shown by Lester/Colella or in the alternative is obvious over Lester/Colella, as discussed above.

As to claims 2, 3, and 24, Lester/Colella show an output indicative of the difference between amount removed to a second location and the amount used comprising the amount of the drug in the DDM.

As to claim 4, Lester/Colella show all elements of the claim including indication the absence of data related to the first medical item since the system tracks and audits the drugs and such auditing of the tracked drugs reveals missing drugs and information.

As to claim 4, Lester/Colella show all elements of the claim except noting the absence of data related to the first type of medical item. However, the examiner takes

official notice that it is notoriously old and well known in the art to provide an indication of missing data related to a tracked item. It would have been obvious to one of ordinary skill in the art to modify the method of Lester/Colella by indicating the missing information in order to flag missing or incorrectly logged items.

Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative under 35 U.S.C. 103(a) as being unpatentable over Lester et al (6,021,392) and Colella et al (6,003,006) incorporated by reference into Lester.

As to claims 1 and 5, Lester et al disclose a method comprising storing a plurality of medical items in a plurality of storage locations within a pharmacy (see e.g., use of bar coded shelf labels as in Fig. 14 of Lester); storing data in a data store corresponding to the medical items (see e.g., col . 15, lines 1-12 of Lester); providing input indicative of taking a first quantity of a first type of medical item from a first storage location for use in second location outside of the pharmacy comprising for stocking a DDM; and providing input indicative of the use of a second quantity of the items at the second location comprising the amount stocked at the DDM. Lester and Colella further show comparing amount removed to a second location and the amount used (stocked at the second location), since the automatically tracks inventory and provides an audit trail in order to provide for re-ordering of drugs and provide the audit trail, the amount sent and the amount received must be compared.

Alternatively, Lester and Colella teach all elements except comparing the amount removed to a second location and the received at the second location (the amount

used). However, the examiner takes official notice that it is notoriously old and well known in the art to compare the amount in and the amount out in order to prevent loss. It would have been obvious to one of ordinary skill in the art to modify the method of Lester/Colella by comparing the amount removed to a second location and the amount used in order to reduce loss and theft.

As to claim 6, Lester/Colella show providing input through a device adjacent the remote storage location indicative of a third quantity taken for use by a patient and including that data in a data store.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lester/Colella.

As to claim 7, Lester/Colella show removing a fourth quantity of a first type of medical item from remote storage comprising expired drugs; providing at least one input indicative of the removal; and storing data indicative of the removal of a fourth quantity. Lester/Colella do not explicitly show that the expired drugs are removed to the pharmacy. However, the examiner takes official notice that to do so is notoriously old and well known in the art. It would have been obvious to one of ordinary skill in the art to modify the method of Lester/Colella by removing the expired drugs to the pharmacy to account for them and dispose of them.

As to claim 8, Lester/Colella show comparing the first, second, third and fourth quantities, since it shows tracking the drugs and auditing the drugs, and in order to do so, the quantities must be compared in order account for the drugs.

As to claim 9, Lester/Colella show providing an output indicative of an unaccounted for portion, since it shows tracking and auditing the drugs and such auditing produces an indication of unaccounted for items.

Alternatively, as to claim 9, Lester/Collela show all elements except providing an output indicative of an unaccounted for items. However, the examiner takes official notice that it is notoriously old and well known in the art to do so. It would have been obvious to one of ordinary skill in the art to further modify the method of Lester/Colella by producing an indication of unaccounted for drugs in order to reduce loss or theft.

Response to Arguments

Applicant's arguments filed 8/10/2005 have been fully considered but they are not persuasive.

Regarding the use of "use", the examiner respectfully disagrees. A further amplification of the reasoning is provided above.

Regarding the allegation of admitted prior art. The examiner withdraws the assertion of admitted prior art regarding the applicant's previous response to the office action of 6/28/2005. As noted above, however, the previous traversal was not adequate due to the reasons put forth above. It is respectfully noted that a full and adequate traversal to the statements of official notice are required.

Regarding the art rejection of Lester/Colella, the examiner notes that due to a typographical error, applicant's attention was drawn to col. 11 of Lester rather than col. 15. Lester shows that data has been entered into the system and stored by the system showing location of the items since the system produces a report for picking items in the pharmacy in which locations are provided.

Regarding the step of comparing, the examiner respectfully disagrees. Lester/Colella show tracking quantity information of items removed the central pharmacy and taking the remote storage. It further tracks items taken from the remote storage for use with patients. The system automatically tracks the inventory at the remote storage locations in order to determine time for reordering. In order to accurately make this determination, the amount taken to the location and the amount taken from the location must be compared.

Regarding the examiner's alleged admission, the examiner respectfully disagrees. The examiner merely argued in the alternative.

Conclusion

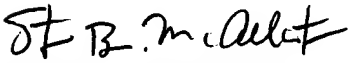
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven B. McAllister whose telephone number is 571-272-6785. The examiner can normally be reached on M-Th 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexander Kalinowski can be reached on 571-272-6771. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Steven B. McAllister
Primary Examiner
Art Unit 3627



Steven B. McAllister

STEVE B. MCALLISTER
PRIMARY EXAMINER